

Remarks/Arguments

Reconsideration of the above-identified application in view of the present amendment is respectfully requested. By the present amendment, claims 1 and 17 have been amended. New claims 21-24 have been added.

Claim Rejections under 35 U.S.C. §102

Claims 1 and 17-20 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,237,875 to Termanini (hereafter "Termanini"). It is respectfully submitted that amended claim 1 is patentable over Termanini and is therefore allowable.

Anticipation requires a single prior art reference that discloses each element of the claim. W.L. Gore & Associates v. Garlock, Inc., 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), cert. denied 469 U.S. 851 (1984). Additionally, the single prior art reference must disclose each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention". Scripps Clinic & Research Foundation v. Genentech Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). "The identical invention must be shown in as complete detail as is contained in the ... claim". Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Amended claim 1 recites a combination of a fixation means and an extraction device that is removably connected to the fixation means. The extraction device includes an inner extraction member, an outer extraction member, and an extraction

handle that rotates relative to the outer and inner extraction members in order to extract a pin in a direction of extraction relative to the outer extraction member and a sleeve. The direction of extraction extends along a longitudinal axis of the outer extraction member. The outer and inner extraction members are axially movable relative to each other and provided with rotary preventing members that directly engage one another in order to prevent the inner extraction member from rotating relative to the outer extraction member during extraction of the pin. The rotary preventing members on the outer extraction member include non-circular cross-sectional parts of a through hole in the outer extraction member. The rotary preventing members of the inner extraction member include non-circular cross-sectional parts. The extraction handle can cooperate with the inner extraction member in order to draw the inner extraction member backwards in the axial direction of extraction when the inner extraction member is inserted into the outer extraction member so that the rotary preventing members directly engage one another.

Termanini does not teach or suggest an extraction device that includes an outer extraction member removably connected to a sleeve. Termanini teaches a compression nail 9 that includes a threaded shaft 5 threadably engaged with a screw head 14. The shaft 5 is positioned within and rotatable relative to an outer tube 10. The screw head 14 has a hexagonal recess 19 for receiving a tool 42 in order to rotate the screw head relative to the shaft 5, causing axial-only movement of the shaft relative to the screw head and the outer tube.

The shaft 5 includes a series of pins 8 that cooperate with angled slots 3 in movable blades 1, 2 which have projections 7 for penetrating bone. By rotating the screw head 14 via the tool 42 relative to the shaft 5, the shaft moves axially relative to the screw head and outer tube 10, thereby causing the pins 8 to move axially relative to the slots 3 in order to extend and retract the blades 1, 2, as shown by the arrows in Fig. 3.

It is clear from Fig. 3 that the portion of the outer tube 10 surrounding the blades 1, 2, which the Examiner asserts constitutes the sleeve of the present invention (Office Action page 4), is integral with the remainder of the outer tube. In other words, the portion of the outer tube 10 surrounding the blades 1, 2 is not removably connected to the remainder of the outer tube. Termanini therefore does not teach or suggest an extraction device that includes an outer extraction member removably connected to a sleeve.

Termanini also does not teach or suggest an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve. The Examiner asserts that the projections 7 on the blades 1, 2 and the portion of the outer tube 10 radially outward of the pins 8 constitute the nail and sleeve, respectively, of the present invention (Office Action page 4). The projections 7 of Termanini, however, move radially inward relative to the outer tube 10 when the screw head 14 rotates relative to the outer tube in order to remove the projections from the surrounding bone. In other words, the projections do not move axially relative to the outer tube 10 when the screw head 14 rotates relative to the outer

tube. Therefore, Termanini does not teach or suggest an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve. Accordingly, it is respectfully submitted that amended claim 1 is patentable over Termanini and is therefore allowable.

Amended claim 17 recites an extraction device having an inner extraction member removably connected to a pin, an outer extraction member removably connected to a sleeve, and an extraction handle that rotates relative to the outer and inner extraction members in order to extract the pin in an extraction direction that extends along a longitudinal axis of the outer extraction member relative to the outer extraction member and a sleeve. The outer and inner extraction members are axially movable relative to each other and provided with rotary preventing members that directly engage one another to prevent the inner extraction member from rotating relative to the outer extraction member during extraction of the pin. The rotary preventing members on the outer extraction member are non-circular cross-sectional parts of a through hole in the outer extraction member. The rotary preventing members of the inner extraction member are non-circular cross-sectional parts.

As noted, Termanini does not teach or suggest 1) an outer extraction member that is removably connected to a sleeve, and 2) an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve. Therefore, Termanini does not teach or suggest every element recited in amended

claim 17. Accordingly, it is respectfully submitted that amended claim 17 is patentable over Termanini and is therefore allowable.

Claims 18-20 depend from claim 17 and are allowable for at least the same reasons as claim 17 and for the specific limitations recited therein.

Claim Rejections under 35 U.S.C. §103

Claims 1, 5-6, 8-9, 12-14, and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,707,373 to Sevrain et al. (hereafter "Sevrain") in view of U.S. Patent No. 6,524,238 to Velikaris et al. (hereafter "Velikaris"). It is respectfully submitted that amended claim 1 is patentable over the combination of Sevrain and Velikaris and is therefore allowable.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Amended claim 1 recites an extraction device including an inner extraction member, an outer extraction member, and an extraction handle that rotates relative to the outer and inner extraction members in order to extract a pin in a direction of extraction relative to the outer extraction member and a sleeve. The direction of extraction extends along a longitudinal axis of the outer extraction member. The inner extraction member is inserted into the outer extraction member and is axially movable relative to the outer extraction member. The outer and inner extraction members are provided with rotary preventing members that directly engage one another in order to prevent the inner extraction member from rotating relative to the outer extraction member during extraction of the pin. The rotary preventing

members on the outer extraction member include non-circular cross-sectional parts of a through hole in the outer extraction member. The rotary preventing members of the inner extraction member include non-circular cross-sectional parts. The extraction handle can cooperate with the inner extraction member in order to draw the inner extraction member backwards in the axial direction of extraction when the inner extraction member is inserted into the outer extraction member so that the rotary preventing members directly engage one another.

The combination of Sevrain and Velikaris does not teach or suggest an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve. Sevrain teaches a fastening instrument 100 that includes a sleeve 102 and a threaded elongated rod 120 positioned within and rotatable relative to the sleeve. The sleeve 102 and rod 120 cooperate to secure first and second fasteners, i.e., a cap 130 and a base 140, to one another to close a craniotomy.

In use, once the base 140 is positioned underneath the skull, a pair of locking posts 112, 114 provided in the distal end 106 of the sleeve 102 are used to secure the distal end to the cap 130 (Fig. 19). The rod 120 is then slid through the cap 130 and the threaded tip 128 of the rod is threadably engaged with internal threads 148 on the stud 142 of the base 140 by rotating the rod in the direction of arrow 146 relative to the sleeve 102 (Fig. 21). The rod 120 is then axially retracted relative to the sleeve 102 (or the sleeve axially advanced relative to the rod) to bring the external threads 144 on the stud 142 into engagement with the internal threads 136 in the cap 130. The sleeve 102 is then rotated via a disc 126 (Fig. 13) in the

direction of arrow 146 to screw the cap 130 into the base 140. After the cap 130 has been fully screwed to the base 140 to lock the cap and the base to one another and the skull, the disc 126 is rotated in the direction of arrow 147, i.e., opposite to the direction of arrow 146, to unscrew the threaded tip 128 of the rod 120 from the stud 142 and remove the fastening instrument 100 from the cap 130 and base 140.

The rod 120 of Sevrain, however, does not extract the base 140 from the skull or any other structure. Rather, the rod 120 maintains the base 140 in engagement with the underside of the bone while the sleeve 102 is rotated to move the cap 130 downward and into threaded engagement with the base. In other words, the base 140 remains positioned beneath the skull at all times – it is not extracted or removed from the bone due to rotation or movement of the rod 120 or any other portion of the fastening instrument 100. In fact, Fig. 19 clearly indicates that the opening in the skull that accommodates the collar 138 of the cap 130 and the stud 142 of the base 140 prevents the base from being extracted from the skull by the rod 120. Accordingly, Sevrain does not teach or suggest an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve as recited in amended claim 1.

The Examiner relies on Velikaris, i.e., the retractable sliding pin 5 and corresponding locking indentation 20, to teach rotary preventing members to prevent rotation between the distal end 106 of the sleeve and the remainder of the sleeve 102 in Sevrain. Such a modification of Sevrain, however, would not change the fact that the base 140 always remains positioned beneath the skull and is

incapable of being extracted therefrom by the rod 120. Accordingly, Velikaris does not cure the deficiencies of Sevrain.

The combination of Sevrain and Velikaris also does not teach or suggest an inner extraction member that is inserted into an outer extraction member and is axially movable relative to the outer extraction member. As clearly shown in Figs. 13 and 19, the distal end 106 of the sleeve 102 is integral with the remainder of the sleeve. Furthermore, there is no indication that the distal end 106 ever rotates or moves axially relative to the remainder of the sleeve 102 during operation of the fastening instrument 100. In fact, the only possible axial movement of the distal end 106 would be downward and away from the remainder of the sleeve 102, as viewed in Fig. 19. This downward movement, however, of the distal end 106 relative to the remainder of the sleeve 102 would decouple the cap 130 from the sleeve 102 and, thus, the sleeve could not rotate the cap in order to secure the cap to the base 140, thereby rendering the fastening instrument 100 inoperable.

The Examiner relies on Velikaris to teach rotary preventing members to prevent rotation between the distal end 106 of the sleeve and the remainder of the sleeve 102 in Sevrain. Such a modification of Sevrain, however, would not affect the ability of the distal end 106 to axially move relative to the remainder of the sleeve 102. Therefore, assuming *arguendo* that the teachings of Velikaris were implemented into the device of Sevrain, the distal end 106 of Sevrain would still not move axially relative to the remainder of the sleeve 102. Accordingly, Velikaris does not cure the deficiencies of Sevrain.

The combination of Sevrain and Velikaris also does not teach or suggest an outer extraction member that is manually holdable in order to prevent the outer extraction member from rotating when an extraction handle is rotated. It is clear from the above that rotation of the rod 120 at any time does not cause rotation of the sleeve 102 and, thus, the sleeve is not manually held to prevent rotation of the sleeve when the rod is rotated. Rather, the rod 120 freely passes through the distal end 106 of the sleeve in order to engage the base 140. Rotation of the rod 120 to thread the threaded tip 128 of the rod onto the internal threads 148 of the base 140 occurs when the cap 130 secured to the sleeve 102 is spaced from the base 140 (see Fig. 21). Therefore, it is impossible for the rotation of the rod 120 to be imparted to the sleeve while the rod is initially threaded onto the base 140. In other words, the sleeve 102 will not be rotated due to the initial rotation of the rod 120 whether the sleeve is held or not.

The rod 120 is reverse rotated once the cap 130 is fully screwed onto the base 140 and rigidly securing the cap and the base to the skull. Due to this rigid connection, reverse rotation of the rod 120 relative to the cap 130 and base 140 to unscrew the rod from the base cannot impart rotation to the sleeve 102, which has its integral distal end 106 rigidly connected to the cap via the locking pins 112, 114. In other words, the sleeve 102 will not be rotated due to reverse rotation of the rod 120 whether the sleeve is held or not. Therefore, manually holding the sleeve 102 during rotation of the rod 120 in either direction does not prevent the sleeve from rotation. Accordingly, Sevrain does not teach or suggest an outer extraction member

that is manually holdable in order to prevent the outer extraction member from rotating when an extraction handle is rotated as recited in amended claim 1.

The Examiner relies on Velikaris to teach rotary preventing members to prevent rotation between the distal end 106 of the sleeve and the remainder of the sleeve 102 in Sevrain. Such a modification of Sevrain, however, would not affect the ability of the rod 120 to rotate and axially translate relative to the sleeve 102, i.e., without imparting rotation to the sleeve. Therefore, assuming *arguendo* that the teachings of Velikaris were implemented into the device of Sevrain, the sleeve 102 of Sevrain would not rotate due to rotation of the rod 120 whether the sleeve is held or not. Accordingly, Velikaris does not cure the deficiencies of Sevrain.

The combination of Sevrain and Velikaris also does not teach or suggest an extraction handle that can cooperate with an inner extraction member in order to draw the inner extraction member backwards in an axial direction of extraction when the inner extraction member is inserted into an outer extraction member. In Sevrain, rotation and/or axial movement of the rod 120 does not affect the axial or radial position of either the distal end 106 or the remainder of the sleeve 102 at any time. In particular, the rod 120 is passed through a passage in the distal end 106 in order to allow the threaded tip 128 of the rod to pass through the distal end and engage the internal threads 148 on the base 140. Likewise, the rod 120 rotates within and relative to the distal end 106 to allow the threaded tip 128 to threadably engage or disengage the internal threads 148 on the base 140. In other words, at no point during operation of the rod 120 does the rod cooperate with the distal end 106 of the sleeve 102 to cause movement thereof. Accordingly, Sevrain does not teach or

suggest an extraction handle that can cooperate with an inner extraction member in order to draw the inner extraction member backwards in an axial direction of extraction when the inner extraction member is inserted into an outer extraction member.

As noted, the teachings of Velikaris would not alter the rotational relationship between the rod 120 and the sleeve 102. Since the distal end 106 of the sleeve 102 is integral with the remainder of the sleeve (Fig. 19), the teachings of Velikaris likewise would not alter the rotational relationship between the rod 120 and the distal end 106. In other words, implementing the retractable sliding pin 5 and corresponding locking indentations 20 of Velikaris into the sleeve 102 and distal end 106 of Sevrain would not cause the rotating rod 120 to impart axial movement upon the distal end. Therefore, Velikaris does not cure the deficiencies of Sevrain. For these reasons, a *prima facie* case of obviousness has not been shown because the combination of Sevrain and Velikaris does not teach or suggest every element recited in amended claim 1. Accordingly, it is respectfully submitted that amended claim 1 is patentable over the combination of Sevrain and Velikaris and is therefore allowable.

Claims 5-6, 8-9, and 12-14 depend from claim 1 and are allowable for at least the same reasons as claim 1 and for the specific limitations recited therein.

Furthermore, claim 5 recites that a tip of the pin is situated in an opening of the sleeve and thereby cooperates with a rear edge of the opening such that the pin, through the cooperation with the rear edge of the opening, draws the sleeve

backwards in the direction of extraction when the sleeve is pulled out of the bone fragment by means of the extraction handle.

Sevrain does not teach or suggest this structure. In Sevrain, the cap 130 and base 140 only cooperate with one another when they are threaded together. When the cap 130 and the base 140 initially engage one another, however, rotation of the cap causes the cap and the base to move closer to one another, i.e., neither the cap nor the base is forced in a direction away from the surface of the skull. In any case, it is movement of the cap 130 that causes movement of the base 140, not the other way around.

When the cap 130 is unthreaded from the base 140, the base remains stationary while the sleeve 102 is rotated in order to unscrew the cap from the base and away from the skull. Furthermore, the cap 130 can only be removed from the skull if it is completely disengaged from the base 140, i.e., the cap and base do not cooperate with one another in any way. In other words, the base 140 does not pull or draw the cap away from the skull during removal of the cap from the skull – the sleeve 102 does.

Moreover, as noted, the cap 130 is connected to the distal end 106 of the sleeve 102 via locking posts 112, 114 such that retraction of the sleeve from the skull when the cap and base 140 are unscrewed causes the cap to be removed from the skull. In other words, it is the sleeve 102 that removes the cap 130 from the skull – not the rod 120. In fact, since the rod 120 is only secured to the base 140 and not the cap 130, the distal end 106 of the sleeve 102 is incapable of removing the cap from the skull. Sevrain therefore does not teach or suggest a pin that, through the

cooperation with a rear edge of an opening in a sleeve, draws the sleeve backwards in the direction of extraction when the sleeve is pulled out of the bone fragment by means of an extraction handle, as recited in claim 5.

The Examiner relies on Velikaris to teach rotary preventing members to prevent rotation between the distal end 106 of the sleeve and the remainder of the sleeve 102 in Sevrain. Such a modification of Sevrain, however, would not affect 1) how the cap 130 cooperates with the base 140 or 2) how the sleeve 102 interacts with the cap to remove the cap from the skull and, thus, Velikaris does not cure the deficiencies of Sevrain. For these reasons, a *prima facie* case of obviousness has not been shown because the combination of Sevrain and Velikaris does not teach or suggest every element recited in claim 5. Accordingly, it is respectfully submitted that claim 5 is patentable over the combination of Sevrain and Velikaris and is therefore allowable.

Amended claim 17 recites an extraction device having an inner extraction member removably connectable to a pin, an outer extraction member, and an extraction handle that rotates relative to the outer and inner extraction members in order to extract the pin in an axial extraction direction relative to the outer extraction member and a sleeve. The inner extraction handle is insertable into the outer extraction member. The outer extraction member is manually engageable to prevent the outer extraction member from rotating when the extraction handle is rotated. The outer and inner extraction members are axially movable relative to each other and provided with rotary preventing members that directly engage one another to prevent the inner extraction member from rotating relative to the outer extraction member

during extraction of the pin. The rotary preventing members on the outer extraction member are non-circular cross-sectional parts of a through hole in the outer extraction member. The rotary preventing members of the inner extraction member are non-circular cross-sectional parts.

As noted, the combination of Sevrain and Velikaris does not teach or suggest 1) an extraction handle that rotates relative to outer and inner extraction members in order to extract a pin in an axial direction of extraction relative to the outer extraction member and a sleeve, or 2) an outer extraction member that is manually holdable in order to prevent the outer extraction member from rotating when an extraction handle is rotated. Accordingly, a *prima facie* case of obviousness has not been shown because the combination of Sevrain and Velikaris does not teach or suggest every element recited in amended claim 17. For these reasons, it is respectfully submitted that amended claim 17 is patentable over the combination of Sevrain and Velikaris and is therefore allowable.

Claims 7 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Termanini in view of U.S. Patent No. 6,053,653 to Tanaka et al. (hereafter "Tanaka"). Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Termanini in view of Tanaka and further in view of U.S. Patent No. 5,571,102 to Cavagna et al. Claims 7, 10, and 11 depend from claim 1 and are allowable for at least the same reasons as claim 1 and for the specific limitations recited therein.

New Claims

Claims 21 and 22 recite that the inner extraction member directly engages the pin. Claims 23 and 24 recite that the extraction handle cooperates with the inner extraction member in order to draw the inner extraction member backwards relative to the outer extraction member in the direction of extraction. It is respectfully submitted that the art of record does not teach or suggest this structure and, thus, claims 21-24 are patentable over the art of record and are therefore allowable.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and allowance of the application is respectfully requested.

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Respectfully submitted,

/James L. Tarolli/

James L. Tarolli

Reg. No. 36,029

TAROLLI, SUNDHEIM, COVELL,
& TUMMINO L.L.P.
1300 East Ninth Street, Suite 1700
Cleveland, Ohio 44114
Phone: (216) 621-2234
Fax: (216) 621-4072
Customer No.: 26,294